

Reduced Exposure/Reduced Risk Tobacco Products: An Examination of the Potential Health Impact and Regulatory Changes

COMMITTEE ON GOVERNMENT REFORM U.S. HOUSE OF REPRESENTATIVES

Thank you very much for the opportunity to appear before this committee to talk about a truly critical issue for global public health.

My name is David Sweanor, and I am counsel to the Non-Smokers' Rights Association [NSRA] in Canada, an organization I have worked for for over 20 years. NSRA has been a primary driver for a very full range of public health policies aimed at reducing the toll from tobacco. These include health-oriented tobacco tax policies, restrictions on tobacco sales, comprehensive restrictions of tobacco advertising and promotion, detailed package-based health information – including picture-based warnings covering 50% of packages and package inserts giving additional health information, comprehensive disclosure of additives and sales data, and regulatory authority over tobacco manufacturing standards. These policies have played a key role in very significant drops in Canadian tobacco consumption, which have outpaced US declines. Last year alone, and largely due to very significant cigarette tax increases, per capita consumption in Canada fell by 8%. I believe that this is two to three times the rate of decline in the US.

In addition to my work in Canada I have, for many years, been very involved in tobacco control issues in this country, and globally. It is because of my interest in global public health, my long-term interest in applying harm reduction principles to tobacco, and the strong policy interactions between Canada and the United States that I welcome the opportunity to speak to you today.

The public health goals for tobacco policy

It is possible to articulate a concise view of the public health goals of tobacco control activities. The ultimate goal is to reduce death and disease as much as is practically possible within the constraints of law and with respect for human rights. To achieve this goal there are essentially three broad areas of intervention. We must expand current efforts that aim to prevent smoking onset and that encourage and facilitate cessation but we must also reduce the toxicity for those who continue to use tobacco.

While many nations have done much to try to prevent onset of smoking, far fewer have made significant strides in promoting and facilitating cessation, and almost none have moved significantly on issues of toxicity reduction. This is a major concern to me since preventing the uptake of smoking, even when successful, will not have a significant impact on disease rates for another 20-30 years due to the lag between the onset of smoking and the development of the resulting diseases. To put this into an American perspective, the World Health Organization estimates that roughly 10 million Americans will die as a direct result of cigarette smoking in the next 20 to 25 years. All of these people are currently smokers, most say they'd rather not be smoking, and only cessation and toxicity reduction can impact on this unfolding tragedy.

In short, the status quo is horrible. Cigarettes dominate the market, and will kill roughly 50% of their long-term users. Most individuals who want or need nicotine on a long-term basis meet this need via cigarettes and far too few turn to FDA approved Nicotine Replacement Therapies such as the patch, oral inhaler, and lozenge. FDA approved products have slowly increased but consumers have far too few choices, the development of long term replacement products have been stymied by FDA regulatory roadblocks, and there has been no meaningful consideration of using these products for long term harm reduction.

There may be a way out of this mess.

Nicotine is the primary reason for tobacco use. It provides various pharmacological effects sought by many smokers. But it is also, especially when delivered through cigarette smoking, highly addictive. Yet nicotine itself is apparently responsible for only a very small part of the health damage caused by tobacco use. The reason smokers are dying in such great numbers is that they are obtaining their nicotine through the repeated inhalation of smoke. Nicotine provides the demand for tobacco, but it is combustion that is the principal reason for the morbidity and mortality.

Simply put, cigarettes are an exceedingly 'dirty' delivery system for the drug nicotine.

Reduced risk products for smokers are a viable concept and, properly regulated and marketed, can complement efforts to reduce smoking onset and assist overall cessation efforts. We should do far more to motivate and facilitate cessation. But for those not currently ready, willing and able to totally cease all forms of tobacco and nicotine, toxicity reduction is the only alternative to a continuation of the current epidemic of smoking-caused disease and death.

The ability to provide reduced-risk forms of nicotine is not merely theoretical. Several countries now permit medicinal nicotine products, such as the patch and gum, to be widely available and to be used in place of cigarettes for purposes such as smoking reduction, temporary abstinence and relapse prevention. Some consumers are also using these products for long-term avoidance of smoking and doing so with no apparent ill effects. Clearly, the risk of these products is miniscule compared to the risk of cigarettes.

In addition, Sweden has witnessed a truly fascinating transition from a market dominated by cigarettes to one where smokeless tobacco is now more commonly used. The smokeless tobacco in that country is manufactured according to standards designed to reduce toxicity, and recent studies from that country have failed to show this form of tobacco to be the cause of any cancer. Recently, the regulatory requirement for a cancer warning on these products was actually removed. Sweden has rates of tobacco use very similar to other Scandinavian countries, but has much lower tobacco-related death rates, and this difference can be largely explained by the fact that so many Swedes use smokeless tobacco rather than smoking cigarettes.

Sweden is an interesting case study for many reasons. Perhaps the key lesson is that it is possible to offer consumer-acceptable alternatives to cigarettes that have massively reduced risks compared to cigarettes. This does not necessarily mean that we should all simply encourage the use of 'snus', but we certainly should look in detail at the Swedish experience when considering the risks and benefits of offering less hazardous substitutes for cigarettes. In fact, given the wealth of experience and data that can be obtained from Sweden [not to mention very different opinions about this data from the Swedes themselves] it is surprising to me that detailed analysis of the Swedish experience has not been more of a priority.

Replacing 'dirtier' delivery systems with cleaner ones is an obvious measure to take in efforts to reduce toxicity for those who are going to continue using nicotine. Different nicotine delivery devices will have differing levels of risk. Theoretically we could place all these products on a spectrum and look at ways to give information and other incentives that would encourage consumers to move toward the lowest risk products that can still meet their needs. And one could also imagine a system of incentives that would encourage manufacturers to work to create products with lower and lower toxicity levels.

But, like most seemingly straightforward public policy solutions it gets rather complicated in the real world. If it were truly easy to prevent a half million deaths a year in this country I am sure these hearings would not even be necessary since the corrective measures would have been taken many years ago.

The complicating issues

We need to avoid making new mistakes and we need to avoid unnecessarily adding to the death and illness caused by past mistakes. Millions of smokers smoke 'light' and 'mild' cigarettes in the false belief that they are actually safer. It took years for independent scientists and governments to discover that these

products are actually part of a massive consumer deception on relative risk. An effective harm reduction strategy must begin with an end to all forms of deception on relative risk and comprehensive science based regulation of all tobacco products and the marketing for those products. There needs to be a governmental agency that knows the whole truth about the relative health risks of different products and that is in a position to insure that consumers are provided the whole truth in a non-misleading way that promotes the overall public health. Without comprehensive regulation both the government and consumers cannot be sure they have complete information or the tools to best protect the public health.

Regulation is only a first step, and is not an end in itself. It needs to be based on clear goals. Here, briefly, are some of the issues I think we need to consider when looking at potential reduced-risk products:

- 1) **What is the degree of certainty that we want to have that a product truly does reduce risk compared to standard cigarettes?** On a one-for-one basis this is not a difficulty when looking at medicinal nicotine products such as the patch and nicotine gum that are already fully regulated. It should also not be a difficulty with low nitrosamine smokeless tobacco, given the massive differences in potential disease risk compared to cigarettes, if there was a mechanism that could stipulate the actual level of nitrosamines and other harmful substances in these products. If all cigarette use were simply replaced by medicinal nicotine and low nitrosamine smokeless tobacco products the death rates would be massively lower. But there are many products, especially combustion-based products, where the degree of risk reduction is by no means understood. There needs to be some system in place that can credibly evaluate the relative risks of all tobacco products.
- 2) **What about the risk from a product that only replaces some cigarettes?** It is quite possible that a product could be far less hazardous than cigarettes, but replace so few of the cigarettes that someone smokes that it would have no appreciable impact on risk. Yet if smokers believe such a product to have significant health benefits they are, once again, being deceived. How can we develop guidance on issues of ‘smoking reduction’?
- 3) **How can we effectively place various current and future products on a ‘continuum of risk’ so that we can communicate to users the information they need to make fully informed decisions?** Many smokers believe that ‘light’ cigarettes are significantly less hazardous than regular cigarettes, which is perhaps the greatest consumer deception of our time. Consumers also believe that the ‘tar’ and nicotine listed on ads is what they actually get from smoking various cigarettes. As shown in Appendix 1, many also believe that nicotine causes cancer and that using smokeless tobacco is as deadly as smoking. In addition most harbor misunderstandings about the workings and potential risks from medicinal nicotine that only serve to keep them from availing themselves of these proven safe and effective means of quitting smoking. This level of confusion about such a critical public health issue is truly alarming, and could possibly even worsen as new and unregulated products hit the market.
- 4) **How can we prevent efforts at toxicity reduction from undermining our efforts on cessation and prevention of uptake?** The main planks of good public policy should be complementary rather than adversarial. If the promise of toxicity reduction reduces quitting or encourages more people to enter [or re-enter] the market the unintended consequences could negate any potential health gains from the intervention. This is the reason that meaningful regulation of both claims and how potential harm reduction products are marketed is critical.
- 5) **Who should communicate messages to the public?** One of the realities of the present environment, and one borne out by the history of foods and drugs prior to the existence of the FDA, is that without strong government oversight those with a vested interest in selling products should not be trusted to communicate full and truthful information. With foods and pharmaceuticals there are now stronger grounds to believe claims due to the intervention of a credible, objective and expert third party. Such third party validation is as important to tobacco companies as it is to public health. Even a tobacco company that tried to tell the truth about a massively reduced-risk product would probably not be believed in today’s environment. It is

critical that FDA be given effective authority over all tobacco products in order to ensure that consumers are not misled about the relative risks of different products, including reduced risk tobacco/nicotine products.

- 6) **How can we be assured that the messages conveyed to the public are being appropriately interpreted?** What if smokers believed that smokeless tobacco was something they could switch to after they developed a smoking related disease like lung cancer? What if they came to believe that all smokeless tobacco [including, say, that sold in Sudan or Central Asia] had the same risks? There appears to be a strong need for an institutionalized form of post-marketing surveillance, both to assess attitudes and behaviors.
- 7) **How do we stay on top of what could be a rapidly changing environment?** Approximately 45 million Americans spend roughly \$80 billion a year buying a dirty drug delivery system that is killing over 400,000 of them – and tens of thousands of non-smokers – annually. If this market were subject to effective FDA regulation that actually promotes competition based on good science - and marketing that is not misleading - private enterprise and informed consumers would cause a marketplace revolution. Just as did the legal reforms on foods and drugs in 1906 and 1938.

These are tough issues. But the need to address them is truly monumental. Your fellow citizens are dying from tobacco use, but they are also dying for want of truthful information on relative risks and from a lack of viable alternatives to cigarettes. There is a need for prompt action. The FDA and FTC already have authority over medicinal nicotine. I would hope that they would begin an immediate examination of how they might use their existing authority to expand the availability of these products and to explore their potential for harm reduction. Smokeless tobacco products could also be a key part of a harm reduction strategy if a federal agency were given the authority to regulate the content of these products and how they are advertised. I would hope that this, too, could be done quickly.

There are no easy answers. There is, instead, a need to balance potential risks and benefits. There is a need to assess the science behind products and the best way to communicate relevant information to consumers, and how best to regulate a market in order to give maximum protection for consumers. There is also a great need to stimulate discussion on how to proceed. It is no longer a question of whether there will be alternatives to cigarettes or whether truthful information on relative risks should be communicated to consumers. It is, instead, an issue of how to evaluate products and of how to communicate information in a way that complements public health goals and provides consumers with much needed information about the relative risks of alternative products.

Thank you for your time,

APPENDIX 1

Data From: *Informing Consumers about the Relative Health Risks of Different Nicotine Delivery Products*, K. Michael Cummings, PhD, MPH, Gary A. Giovino, PhD, Maansi A. Bansal, Andrew Hyland, PhD, Jan Hastrup, PhD, Berwood Yost, National Conference on Tobacco or Health New Orleans, Louisiana, November 2001



